IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC. Defendant.	)	C.A. No. 21-1015-JLH **DEMAND FOR JURY TRIAL**
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter-Defendants.	)	

FINAL JURY INSTRUCTIONS

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1. GENERAL INSTRUCTIONS

1.1 INTRODUCTION[1]

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case. Please listen very carefully to everything I say. In following my instructions, you must follow all of them, including the ones I gave to you on Monday at the start of the case and the ones I have given during trial. You may not single out some and ignore others. They are all important.

Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer. You will have a written copy of these instructions with you in the jury room for your reference during deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case. We will go over that later.

I will start by explaining your duties and the general rules that apply in every civil case. Then I will explain some rules that you must use in evaluating particular testimony and evidence. Then I will explain the positions of the parties and the law you will apply in this case. And last, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

[1] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (slight edits).

1.2 JURORS' DUTIES[2]

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts.

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on the issues presented. I will instruct you about the burden of proof shortly. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes any instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not guess or speculate, and do not let any bias, sympathy, or prejudice that you may feel toward one side or the other influence your decision in any way.

[2] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (slight edits).

1.3 EVIDENCE DEFINED[3]

You must make your decision based only on the evidence that you saw and heard here in the courtroom. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way.

The evidence in this case includes only what the witnesses said while they were testifying under oath, including deposition testimony that has been played by video or read to you, the exhibits that I allowed into evidence, and any facts that the parties agreed to by stipulation, and I instruct you to accept as true.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. The lawyers' questions and objections are not evidence. My legal rulings are not evidence. You should not be influenced by a lawyer's objection or by my ruling on that objection. None of my comments and questions are evidence. The notes taken by any juror are not evidence.

Certain reproductions, charts, summaries, and graphics have been used to illustrate certain evidence and testimony from witnesses. Unless I have specifically admitted them into evidence, these reproductions, charts, summaries, and graphics are not themselves evidence, even if they refer to, identify, or summarize evidence.

During the trial I may not have let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. Sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. You must completely ignore all of these things. Do not speculate about what a witness might have said or what an exhibit might have shown. These things are not

[3] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *EIS, Inc. v. Intihealth Ger GmbH*, C.A. No. 19-1227, D.I. 662 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (slight edits).

evidence, and you are bound by your oath not to let them influence your decision in any way. Make your decision based only on the evidence, as I have defined it here, and nothing else.

1.4 DIRECT AND CIRCUMSTANTIAL EVIDENCE[4]

During the preliminary instructions, I told you about "direct evidence" and "circumstantial evidence." I will now remind you what each means.

Direct evidence is evidence like the testimony of any eyewitness which, if you believe it, directly proves a fact. If a witness testified that she saw it raining outside, and you believed her, that would be direct evidence that it was raining.

Circumstantial evidence is a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weights that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

[4] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *EIS, Inc. v. Intihealth Ger GmbH*, C.A. No. 19-1227, D.I. 662 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH).

1.5 CONSIDERATION OF EVIDENCE[5]

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.

[5] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH).

1.6 USE OF NOTES[6]

You may have taken notes during trial to assist your memory. As I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency to attach undue importance to matters which one has written down. Some testimony that may not seem important at the time presented, and thus not written down, may take on greater importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence and are by no means a complete outline of the proceedings or a list of the highlights of the trial.

Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

[6] Source: *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH).

1.7 CREDIBILITY OF WITNESSES[7]

You are the sole judges of each witness's credibility. You may believe everything a witness says, or part of it, or none of it. You may consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witness's manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

In determining the weight to give to the testimony of a witness, you may ask yourself whether there is evidence tending to prove that the witness testified falsely about some important fact or whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he or she gave at the trial in person or by deposition testimony played by video or read to you. You have the right to distrust such witness's testimony and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testify.

[7] Source: *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW).

1.8 EXPERT WITNESSES[8]

During the trial, you heard testimony from expert witnesses. When knowledge or special skill in a technical or business subject matter might be helpful to the jury, a person who has that special training or experience in that technical or business field-called an expert witness is permitted to state his or her opinion on those technical or business matters. However, you are not required to accept that opinion. As with any other witness, it is up to you to judge the credentials and credibility of the expert witness and decide whether to rely upon his or her testimony.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. You may consider each expert opinion received in evidence in this case and give it such weight as you think it deserves. If you decide that the opinion of an expert witness is not based upon sufficient education and experience, or if you conclude that the reasons given in support of the opinion are not sound, or if you feel that the opinion is outweighed by other evidence, you may disregard the opinion in whole or in part.

[8] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW).

1.9 DEPOSITION TESTIMONY[9]

During the trial, certain testimony was presented to you through depositions that were read into evidence or presented as video. Regardless of how it was presented, this testimony must be given the same consideration you would give it had the witness appeared live in court. Like the testimony of a live witness, the statements made in a deposition are made under oath and are considered evidence that may be used to prove particular facts. The deposition testimony may have been edited or cut to exclude irrelevant testimony as the parties have only a limited amount of time to present you with the evidence. You should not attribute any significance to the fact that the deposition videos may appear to have been edited, or only portions were read into evidence.

[9] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (with additions).

1.10 BURDENS OF PROOF[10]

In any legal action, facts must be proven by a required standard of evidence known as the "burden of proof." In a case such as this, there are two different burdens of proof that are used. The first is called "preponderance of the evidence." The second is called "clear and convincing evidence." I told you about these two standards of proof during my preliminary instructions to you and I will now remind you what they mean.

Nippon Shinyaku has the burden of proving the amount of any monetary damages associated with its patent infringement claims by a preponderance of the evidence. Sarepta and UWA also have the burden of proving the amount of any monetary damages associated with their patent infringement claims by a preponderance of the evidence. That means that the parties have to prove to you, in light of all the evidence, that what they claim is more likely true than not true.

In addition, Nippon Shinyaku and NS Pharma, on one side, and Sarepta, on the other, are each challenging the validity of the other side's asserted patents. Each side has the burden of proving that the asserted patents are invalid by clear and convincing evidence. Clear and convincing evidence means that it is highly probable that the fact is true. Proof by clear and convincing evidence is a higher burden of proof than a preponderance of the evidence.

You may have heard of the "beyond a reasonable doubt" burden of proof from criminal cases. That requirement is the highest burden of proof in our judicial system. It applies only in

[10] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW) (conforming edits); *EIS, Inc. v. Intihealth Ger GmbH*, C.A. No. 19-1227, D.I. 662 (GBW) (conforming edits); *CAO Lighting Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW).

criminal cases and has nothing to do with a civil case like this one. You should therefore not consider it in this case.

2. THE PARTIES AND THEIR CONTENTIONS[11]

As I did at the start of the case, I will first give you a summary of each side's contentions in this case. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

NS Patents:

1. For each claim asserted by Nippon Shinyaku, whether Sarepta has proven by clear and convincing evidence that the claim is obvious in light of Popplewell et al., *Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials*, 20(2) NEUROMUSCULAR DISORDERS 102 (2010) ("Popplewell 2010"); and/or Sazani et al., *Safety Pharmacology and Genotoxicity Evaluation of AVI-4658*, 29(2) INT'L J. TOXICOLOGY 143 (2010) ("Sazani 2010").
2. If there are NS Patent claims where Sarepta has not proven those claims are invalid, whether Nippon Shinyaku has proven by a preponderance of the evidence that it suffered damages as a result of the infringement and, if so, the amount of such damages.
3. If there are NS Patent claims where Sarepta has not proven those claims are invalid, whether Nippon Shinyaku has proven by a preponderance of the evidence that Sarepta's infringement was willful. If you decide that any infringement was willful, that decision should not affect any damages award you make. I will take willfulness into account later.

Wilton Patent:

1. For each claim asserted by Sarepta and UWA, whether Nippon Shinyaku and/or NS Pharma have proven by clear and convincing evidence that the claim is invalid for lack of written description.

[11] FCBA Model Patent Jury Instructions B.1 (conforming edits).

2. For each claim asserted by Sarepta and UWA, whether Nippon Shinyaku and/or NS Pharma have proven by clear and convincing evidence that the claim is invalid for lack of enablement.

3. If Nippon Shinyaku and NS Pharma have not proven the asserted claim of the Wilton Patent is invalid, whether Sarepta has proven by a preponderance of the evidence that it suffered damages as a result of the infringement and, if so, the amount of such damages.

4. If Nippon Shinyaku and NS Pharma have not proven the asserted claim of the Wilton Patent is invalid, whether Sarepta has proven by a preponderance of the evidence that Nippon Shinyaku's and NS Pharma's infringement was willful. If you decide that any infringement was willful, that decision should not affect any damages award you make. I will take willfulness into account later.

3. PATENTS

3.1 PATENT CLAIMS GENERALLY[12]

Before you can decide many of the issues in this case, you will need to understand the role of the patent "claims." The patent claims are the numbered sentences at the end of a patent. The claims are important because the words of a claim define the scope of the patent right. The figures and text in the rest of the patent provide a description and/or examples of the invention and provide a context for the claims, but the claims define the extent of the patent's coverage.

Here, you will need to understand what each of the asserted claims covers in order to decide whether or not that claim is invalid.

[12] *EIS, Inc. v. Intihealth Ger GmbH*, C.A. No. 19-1227, D.I. 662 (GBW) (conforming edits).

3.2 INDEPENDENT AND DEPENDENT CLAIMS[13]

Claims can be stated in two different ways in a patent. The first way a patent claim can be stated is in the form of an "independent" claim. An "independent" claim does not refer to any other claim of the patent. An independent claim is read alone to determine its scope.

For example, claim 3 of the '092 Patent, which is one of the NS Patents, is an independent claim. You know this because claim 3 does not refer to any other claims. Accordingly, the words of this claim are read by themselves in order to determine what the claim covers.

The second way a claim can be stated is in the form of a "dependent" claim. A "dependent" claim does not itself recite all the requirements of the claims, but instead, incorporates the requirements of another claim or claims and adds its own additional requirements. In this way, the claim "depends" on another claim or claims. Accordingly, to determine what a dependent claim covers, it is necessary look at both the dependent claim and any other claims from which it depends.

For example, claim 3 of the '741 Patent is a dependent claim. If you look at claim 3, it refers to claim 1. Therefore, to determine what claim 3 of the '741 Patent covers, you must consider both the words of claims 1 and 3 together.

[13] *EIS, Inc. v. Intihealth Ger GmbH*, C.A. No. 19-1227, D.I. 662 (GBW) (conforming edits); *Cap-XX, Ltd. v. Maxwell, Techs., Inc.*, C.A. No. 19-1733, D.I. 314 (JLH) (similar).

3.3 CLAIM CONSTRUCTION[14]

It is my job as a judge to define what the terms of the asserted claims mean and to instruct you about these meanings. You must accept the meanings I give you and apply those meanings to the issues that you are asked to decide. You must ignore any different interpretation given to these terms by the witnesses or by attorneys. I instruct you that the following claim terms have the following definitions.

With respect to the asserted claims of the Wilton Patent:

Term in the Wilton Patent	Claim	Court's Construction
"a base sequence"	'851 Patent, claim 1	Plain and ordinary meaning, which means "any sequence of bases that is part of the antisense oligonucleotide" and "requires 100% complementarity to consecutive bases of a target region of exon 53 throughout the entire length of the antisense oligonucleotide."
"a target region"	'851 Patent, claim 1	Plain and ordinary meaning, which means "a segment of the pre-mRNA"
"exon 53 of the human dystrophin pre-mRNA"	'851 Patent, claim 1	Plain and ordinary meaning, which means "the pre-mRNA transcribed from exon 53 of the human dystrophin gene"
"the target region is within annealing site H53A(+23+47) and annealing site H53A(+39+69)"	'851 Patent, claim 1	"the target region is within nucleotides +23 to +69 of exon 53 of the human dystrophin pre-mRNA"
"in which uracil bases are thymine bases"	'851 Patent, claim 1	"the antisense oligonucleotide has thymine bases instead of uracil bases"

[14] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW) (conforming edits); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW).

If I have not provided a specific definition for a given term, you are to use the ordinary meaning of that term. You should not take my definition of the language of the claims as an indication that I have a view regarding how you should decide the issues that you are being asked to decide, such as invalidity. These issues are yours to decide.

4. INFRINGEMENT

4.1 WILLFUL INFRINGEMENT[15]

In this case, Sarepta acknowledges that it infringes the NS Patents, and Nippon Shinyaku and NS Pharma acknowledge that they infringe the Wilton Patent. Nippon Shinyaku argues that Sarepta has willfully infringed the NS Patents, and Sarepta argues that Nippon Shinyaku and NS Pharma have willfully infringed the Wilton Patent. You must address whether or not each side's infringement was willful.

To prove willful infringement of a claim, the party asserting infringement must persuade you that it is more likely true than not that the infringer intentionally infringed at least one asserted claim. You must base your decision on the infringer's knowledge and actions at the time of infringement. Evidence that the infringer had knowledge of the patent at the time of infringement by itself is not sufficient to show willfulness. Rather, to show willfulness, you must find that the infringer engaged in additional conduct evidencing a deliberate disregard of the patent rights of the party asserting infringement.

In deciding whether the infringer willfully infringed, you may consider all of the facts surrounding the infringement including: whether the infringer intentionally copied the patented technology in developing its accused products; whether the infringer knew, or should have known, that its conduct involved an unreasonable risk of infringement of the asserted patent; and whether the infringer had a reasonable belief that at the time of infringement that its products did not infringe the asserted patent or that the patent was invalid.

As I mentioned before, if you determine that any infringement was willful, you may not allow that decision to affect the amount of any damages award you give for infringement.

[15] *WR Grace & Co.-Conn. v. Elysium Health, Inc*., C.A. 1:20-cv-01098, D.I. 310 (GBW).

5. PATENT INVALIDITY

5.1 PATENT INVALIDITY - GENERALLY[16]

I will now instruct you on the rules you must follow in deciding whether or not Nippon Shinyaku and NS Pharma and Sarepta have proven that asserted claims of the other party's patents are invalid. To prove that any claim of a patent is invalid, the party challenging validity must persuade you by clear and convincing evidence, that is, you must be left with a clear conviction that the claim is invalid.

You must determine whether each asserted claim is invalid on a claim-by-claim basis. As I instructed you earlier, there are independent claims and dependent claims in a patent. Finding the broader independent claim to be invalid does not mean the narrower dependent claims are also invalid. However, if you find a narrower dependent claim to be invalid, you must find the broader independent claim from which it depends is also invalid.

[16] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW) (conforming edits).

5.2 PERSON OF ORDINARY SKILL IN THE ART

The question of invalidity of a patent claim is determined from the perspective of a hypothetical "person of ordinary skill in the art" in the field of the asserted invention as of the patent's effective filing date.[17]

To determine the validity or invalidity of the patent claims, you must consider the level of ordinary skill in the field of the invention at the time of the invention.[18]

In this case, the parties agree[19] that a person of ordinary skill in the art is:

An individual that has an M.D., Ph.D., or lower degree with expertise in molecular biology, biochemistry or a related area, and experience with neuromuscular or genetic diseases and/or designing and testing antisense oligonucleotides for splice-site switching/exon skipping applications. The POSA would have general knowledge of antisense oligonucleotide chemical modifications to the backbone, nucleobases and other manipulations that can alter the activity of the antisense molecule, as well as delivery methods for antisense oligonucleotides. A POSA would also have general knowledge regarding using antisense oligonucleotides in cell-free, cell-based and/or in vivo experiments, as well as DMD models and the use of antisense oligonucleotides to induce skipping of DMD exons to correct the open reading frame of the RNA transcripts.

[17] Source: *WR Grace & Co.-Conn. v. Elysium Health, Inc.*, C.A. 1:20-cv-01098, D.I. 310 (GBW).

[18] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW).

[19] Given that both parties' experts agree that the definition of a person of ordinary skill in the art does not alter their analyses and the parties agree that they will not raise arguments or question witnesses (e.g., by cross-examination) regarding the differences between the competing definitions, NS's definition can be the instruction to the jury.

5.3 PRIOR ART GENERALLY[20]

I will now instruct you on a challenge to the NS Patents based on prior art. Under the patent laws, in order for someone to be entitled to a patent, the invention must actually be "new" and not obvious over what came before, which is referred to as prior art. Prior art is considered in determining whether the claims of the asserted patents are anticipated or obvious. Prior art may include items that were publicly known or that have been publicly used or offered for sale before the priority date, or references, such as publications or patents, published before the priority date that disclose the claimed invention or elements of the claimed invention.

Sarepta contends that the following is prior art against the NS patents:

- Popplewell et al., *Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials*, 20(2) NEUROMUSCULAR DISORDERS 102 (2010) ("Popplewell 2010");
- Sazani et al., *Safety Pharmacology and Genotoxicity Evaluation of AVI-4658*, 29(2) INT'L J. TOXICOLOGY 143 (2010) ("Sazani 2010").

[20] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW) (conforming edits).

5.4 OBVIOUSNESS[21]

Sarepta contends that each of the NS Patents is invalid because the claimed invention(s) would have been "obvious."

A claimed invention is invalid as "obvious" if it would have been obvious to persons of ordinary skill in the art in the field of the invention as of August 31, 2011. Obviousness may be shown by considering one or more than one item of prior art.

In deciding obviousness, you must avoid using hindsight; that is, you should not consider what is known today or what was learned from the teachings of the patent. You should not use the patent as a road map for selecting and combining items of prior art. You must put yourself in the place of a person of ordinary skill in the art as of August 31, 2011.

The following factors must be evaluated to determine whether Sarepta has established that the claimed invention is obvious:

1. The scope and content of the prior art relied upon by Sarepta;

2. The differences, if any, between each claim of the NS Patents that Sarepta contends are obvious and the prior art;

3. The level of ordinary skill in the art as of August 31, 2011; and

4. Additional considerations, if any, that indicate that the claims were obvious or not obvious.

Each of these factors must be evaluated, although they may be analyzed in any order, and you must perform a separate analysis for each of the claims. Sarepta must prove by clear and convincing evidence that the invention would have been obvious. Again, you must undertake this analysis separately for each claim that Sarepta contends is obvious.

[21] Source: AIPLA Model Patent Jury Instructions 7.0 (conforming edits); *Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH-SRF, D.I. 488 (conforming edits).

I will now explain each of the four factors in more detail.

5.5 OBVIOUSNESS – THE FIRST FACTOR: SCOPE & CONTENT OF THE PRIOR ART[22]

In deciding obviousness, the parties agree that the prior art includes the following items received into evidence during the trial:

- Popplewell et al., *Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials*, 20(2) NEUROMUSCULAR DISORDERS 102 (2010) ("Popplewell 2010");
- Sazani et al., *Safety Pharmacology and Genotoxicity Evaluation of AVI-4658*, 29(2) INT'L J. TOXICOLOGY 143 (2010) ("Sazani 2010").

[22] Source: AIPLA Model Patent Jury Instructions 7.1 (conforming edits); *Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH-SRF, D.I. 488 (conforming edits).

5.6 OBVIOUSNESS – SECOND FACTOR: DIFFERENCES BETWEEN THE CLAIMED INVENTION & THE PRIOR ART[23]

You should analyze whether there are any relevant differences between the prior art and the claimed invention from the view of a person of ordinary skill in the art as of August 31, 2011. Your analysis must determine the impact, if any, of such differences on the obviousness or nonobviousness of the claimed invention as a whole, and not merely some portion of it.

In analyzing the relevance of the differences between the claimed invention and the prior art, you do not need to look for precise teaching in the prior art directed to the subject matter of the claimed invention. You may consider the inferences and creative steps that a person of ordinary skill in the art would have employed in reviewing the prior art as of August 31, 2011. For example, if the claimed invention combined elements known in the prior art and the combination yielded results that were predictable to a person of ordinary skill in the art at the time of the invention, then this evidence would make it more likely that the claim was obvious. On the other hand, if the combination of known elements yielded unexpected or unpredictable results, or if the prior art teaches away from combining the known elements, then this evidence would make it more likely that the claim that successfully combined those elements was not obvious.

Importantly, a claim is not proven obvious merely by demonstrating that each of the elements was independently known in the prior art. Most, if not all, inventions rely on building blocks long-known, and claimed discoveries almost of necessity will likely be combinations of what is already known. Therefore, you should consider whether a reason existed at the time of the invention that would have prompted a person of ordinary skill in the art in the relevant field to combine the teachings in the way the claimed invention does. The reason could come from the

[23] Source: AIPLA Model Patent Jury Instructions 7.2 (conforming edits); *Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH-SRF, D.I. 488 (conforming edits).

prior art, the background knowledge of one of ordinary skill in the art, the nature of any problem or need to be addressed, market demand, or common sense. [**Sarepta's Proposal:** The greater the structural similarity between the prior art compound and the claimed compound, the greater the motivation to combine and reasonable expectation of success.[24] The prior art may motivate a person of ordinary skill in the art to do more than one thing.[25]] [**Nippon Shinyaku's and NS Pharma's Proposal:** N/A][26]

If you find that a reason existed as of August 31, 2011 to combine the elements of the prior art to arrive at the claimed invention, and there would have been a reasonable expectation of success for doing so, this evidence would make it more likely that the claimed invention was obvious.

Similarly, you may consider the possibility that a reference teaches away from the claimed invention. A reference teaches away from the invention when it would have discouraged a person of ordinary skill in the art as of August 31, 2011 from practicing the claimed invention, or when such a person would be led in a different direction than practicing the claimed invention.

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[24] *Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1385 (Fed. Cir. 2018) ("Our cases have held that the greater the structural similarity between the compounds, the greater the motivation to combine and reasonable expectation of success. . . . The opposite is true, too: the less the structural similarity, the less the motivation to combine and the reasonable expectation of success."); see also *Sun Pharm. Indus., Inc. v. Incyte Corp.*, No. 2019-2011, 2023 WL 5370639, at *4 (Fed. Cir. Aug. 22, 2023) (same).

[25] *See Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 97 F.4th 915, 930 (Fed. Cir. 2024) ("A POSA can be motivated to do more than one thing (in other words, there was motivation both for the deltoid and gluteal muscle) and Teva did not need to show that a POSA would be singularly motivated to use the deltoid injection site.") (citing *Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1328 (Fed. Cir. 2017)).

[26] Nippon Shinyaku's and NS Pharma's Position: The AIPLA Model Jury Instructions and the instructions in *Sight Sciences, Inc. v. Ivantis, Inc.*, No. 21-01317, D.I. 488, do not include these additional statements, and the inclusion of such will only serve to confuse the jury.

You must undertake this analysis separately for each claim that Sarepta contends would have been obvious.

In comparing the scope and content of each prior art reference to a patent claim, you may find that inherency may supply a claim element that is otherwise missing from the explicit disclosure of a prior art reference. The inherent presence of an element so found by you may be used in your evaluation of whether the claimed invention would have been obvious in view of the prior art. But, to rely on inherency to establish the existence of a claim element in the prior art in an obviousness analysis, that element necessarily must be present in, or the natural result of, the combination of elements explicitly disclosed by the prior art. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from an explicit disclosure is not sufficient to find inherency. However, if the disclosure is sufficient to show that the natural result flowing from the explicit disclosure would result in the claim element in question, inherency may be found. Something inherent from the explicit disclosure of the prior art must be limited when applied in an obviousness analysis and used only when the inherent element is the natural result of the combination of prior art elements explicitly disclosed. An important consideration when determining whether a reference inherently discloses a previously unknown property of something is whether that property is unexpected. Although all properties of something are inherently part of that thing, if a property is found to be unexpectedly present, then the property may be nonobvious.

5.7 OBVIOUSNESS – THE THIRD FACTOR: LEVEL OF ORDINARY SKILL[27]

To determine the obviousness of the invention, you must determine the level of ordinary skill in the field of the invention at the time of August 31, 2011. As mentioned earlier, you must consider and assess this factor before reaching your conclusion in this case.

The person of ordinary skill is presumed to know all prior art that you have determined to be reasonably relevant. The person of ordinary skill is also a person of ordinary creativity that can use common sense to solve problems.

[27] Source: AIPLA Model Patent Jury Instructions 7.3 (conforming edits); *Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH-SRF, D.I. 488 (conforming edits).

5.8 OBVIOUSNESS – THE FOURTH FACTOR: OTHER CONSIDERATIONS[28]

As part of deciding the issue of obviousness for each claimed invention, you must also consider certain factors, which may help to determine whether the invention would have been obvious. These factors are sometimes referred to as secondary considerations of non-obviousness. No factor alone is dispositive, and you must consider the obviousness or non-obviousness of the invention as a whole. Certain of these factors include:

1. Were products covered by the claim commercially successful due to the merits of the claimed invention rather than due to advertising, promotion, salesmanship, or features of the product other than those found in the claim?
2. Was there a long-felt need for a solution to the problem facing the inventors, which was satisfied by the claimed invention?
3. Did others try, but fail, to solve the problem that was solved by the claimed invention?
4. Did others copy the claimed invention?
5. Did the claimed invention achieve unexpectedly superior results over the closest prior art?
6. Did others in the field praise the claimed invention or express surprise at the making of the claimed invention?

Answering all, or some, of these questions "yes" may suggest that the claim was not obvious. These factors are relevant only if there is a direct connection, or nexus, between the factor and the invention covered by the patent claim. Even if you conclude that some of the above factors have been established, those factors should be considered along with all the other evidence in the

[28] Source: AIPLA Model Patent Jury Instructions 7.4 (conforming edits); *Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH-SRF, D.I. 488 (conforming edits).

case in determining whether Sarepta has proven that the claimed invention would have been obvious.

[Nippon Shinyaku's and NS Pharma's Proposal: Nippon Shinyaku is entitled to a rebuttable presumption of nexus between the asserted evidence of secondary considerations and a patent claim if it shows that the asserted evidence is tied to a specific product and that the product is the invention claimed (i.e., that the specific product is coextensive with the patented invention).

However, for purposes of evaluating secondary considerations, a finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations; to the contrary, the patentee is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the direct result of the unique characteristics of the claimed invention.[29]] [**Sarepta's Proposal:**[30] N/A]

There are also factors that, if established, may suggest that the claim was obvious. One such factor is whether the claimed invention was independently and simultaneously invented within a comparatively short amount of time. If you answer "yes" to that question, it may suggest that the claim was obvious.

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[29] *Sunoco Partners Marketing & Terminals LP v. Powder Springs Logistics, LLC*, C.A. No. 17-1390, D.I. 766 (LPS-CJB) (conforming edits).

[30] Sarepta's Position: Sarepta objects to Nippon Shinyaku's and NS Pharma's proposed language regarding the presumption of nexus. The AIPLA model instructions adequately address the law regarding nexus. *See Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH-SRF, D.I. 488. Moreover, Nippon Shinyaku and NS Pharma include only portions of the instructions on the presumption of nexus from its cited authority. *See Sunoco Partners Marketing & Terminals LP v. Powder Springs Logistics, LLC*, C.A. No. 17-1390, D.I. 766 (LPS-CJB). To the extent the court determines that an instruction on the presumption of nexus is appropriate, Sarepta reserves the right to add additional detail before the jury receives the final instructions.

5.9 WRITTEN DESCRIPTION[31]

[Nippon Shinyaku's and NS Pharma's Proposal: The patent law contains certain requirements for the part of the patent called the specification. Nippon Shinyaku and NS Pharma contend that the asserted claim of the Wilton Patent is invalid because the specification of the patent does not contain an adequate written description of the claimed invention.

Nippon Shinyaku and NS Pharma bear the burden of establishing by clear and convincing evidence that each of the asserted claims is invalid for lack of written description.

In deciding whether the specification satisfies the written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent when the application was filed. The application leading to the Wilton Patent is considered filed as of June 28, 2005. The written description requirement is satisfied if a person having ordinary skill in the art at the time of the priority date of the patent would have recognized, from reading the patent specifications, that the inventor described the full scope of the invention on or before the priority date.

The written description requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. The specification is not required to expressly include what is well-known to a person of ordinary skill in the art at the priority date. The level of required disclosure depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and other considerations appropriate to the subject matter.

[31] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Jazz Pharm., Inc. v. Avadel CNS Pharm. LLC*, No. 21-691, D.I. 572 (GBW) (conforming edits); *Amgen Inc. v. Sanofi*, No. 14-1317, D.I. 812 (conforming edits); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1340-42 (Fed. Cir. 2021).

Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, those inherent properties may be relied upon for written description support. To be inherent, the feature that is alleged to have been inherent must necessarily have existed in the specification. The fact that the feature is likely to have existed is not sufficient. It is not required, however, that persons of ordinary skill recognize or appreciate the inherent disclosure at the time the patent application was filed. The written description requirement does not demand either examples or an actual reduction to practice.

In this case, the asserted claim of the Wilton Patent is directed to a "genus," which is a group of distinct chemical compounds that each meet all of the claim limitations. To show possession of a genus of functional chemical structures, the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result.[32] It is not sufficient to merely draw a fence around the outer limits of a genus.[33] The question you must decide is whether the specification discloses all of the functional chemical compounds falling within the genus, specifically, as something that the inventors actually invented.[34] If the disclosed species only abide

[32] *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014) ("When a patent claims a genus using functional language to define a desired result, 'the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'") (quoting *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

[33] *Ariad Pharm.*, 598 F.3d at 1350 ("But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.").

[34] *PureCircle USA Inc. v. SweeGen, Inc.*, No. 2022-1946, 2024 WL 20567, at *3 (Fed. Cir. Jan. 2, 2024) ("There, the patentee argued that 'one of ordinary skill in the art . . . would have known how to test every possible variant at that position and thus would have found the claimed variants as a matter of course.' We explained that '[t]he question before us is not whether one of ordinary skill in the art presented with the [relevant] application would have been enabled to take those final

in a corner of the genus, one has not described the genus sufficiently to show that the inventors invented, or had possession of, the entire functional genus. They only described a portion of it.[35]

One way to consider whether the combination of words, structures, figures, diagrams, formulas, etc., contained in the specification at issue is sufficient for a claimed genus is to assess whether the specifications (1) include a representative number of species, i.e. example compounds, falling within the scope of the claimed genus, or (2) describe structural features common to the members of the claimed genus, so that a person of ordinary skill in the art can "visualize or recognize" the members of the claimed genus.

With respect to satisfying written description by the disclosure of a representative number of species, there are no hard and fast rules concerning the number of species that constitutes a "representative number." The specifications need not describe every species in a claimed genus in order to meet the written description requirement. Instead, the specification needs to show that the inventors have truly invented the claimed genus, i.e., that the inventor has conceived of and described sufficient representative species encompassing the breadth of the claimed genus. When there is a substantial variation within the claimed genus, the specification must describe sufficient species that are representative of the full variety or scope of the claimed genus. Where the field of art is unpredictable, disclosure of more species is necessary to adequately show possession of the

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steps, but whether the [relevant] application "discloses the [variants] to him, specifically, as something appellants actually invented."'") (quoting *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1350 (Fed. Cir. 2013)).

[35] *AbbVie*, 759 F.3d at 1299-1300 ("One factor in considering the question is how large a genus is involved and what species of the genus are described in the patent. If the genus is not large or, even if it is, the specification discloses species representing the genus throughout its scope, the requirement may be met. On the other hand, analogizing the genus to a plot of land, if the disclosed species only abide in a corner of the genus, one has not described the genus sufficiently to show that the inventor invented, or had possession of, the genus. He only described a portion of it.")

entire genus.[36] Additionally, one disclosed species cannot provide written description for a claimed genus with substantial size and/or variation.[37] However, the written description requirement does not require inventors, at the time of their application for a patent, to reduce to practice and be in physical possession of every species within the genus.

To satisfy written description by the disclosure of structural features common to each member of the genus, the inventors must describe structures common across the claimed compounds themselves.[38] Further, it is not enough for species to merely share certain structure. The common structural features must correlate with the claimed function, such that one can distinguish functional from non-functional compounds based on the common structural feature.[39] Functional claim language can meet the written description requirement when either the

[36] *Synthes USA, LLC v. Spinal Kinectics, Inc.*, 734 F.3d 1332, 1344 (Fed. Cir. 2013) ("[I]f the art is unpredictable, then disclosure of more species is necessary to adequately show possession of the entire genus.") (quoting *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124 (Fed. Cir. 2004)).

[37] *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1340-42 (Fed. Cir. 2021) (no written description where patent "discloses only one CD19-specific scFv" but claimed a "genus of functional CD19-specific scFvs.").

[38] *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378-79 (Fed. Cir. 2017) ("Further, the 'newly characterized antigen' test flouts basic legal principles of the written description requirement. Section 112 requires a 'written description of the invention.' But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen. The test thus contradicts the statutory 'quid pro quo' of the patent system where 'one describes an invention, and, if the law's other requirements are met, one obtains a patent.'") (quoting *Ariad Pharm.*, 598 F.3d at 1345).

[39] *Juno*, 10 F.4th at 1339 ("It is undisputed that scFvs generally have a common structure, as described by Dr. Brocker. But, as Dr. Brocker acknowledged, an scFv with the same general common structure but with a different amino acid sequence would recognize a different antigen. Dr. Brocker also testified that all scFvs have a common structure, regardless of whether they bind. The '190 patent not only fails to disclose structural features common to scFvs capable of binding specific targets, it also fails to disclose a way to distinguish those scFvs capable of binding from scFvs incapable of binding those targets.").

specification or what was known in the art at the time of the filing date establishes a reasonable structure-function correlation.]

[**Sarepta's Proposal:**[40] The patent law contains certain requirements for the part of the patent called the specification. The written description requirement is designed to ensure that the inventor was in possession of the full scope of claimed invention as of the patent's effective filing date. Nippon Shinyaku and NS Pharma contend that the asserted claim of the Wilton Patent does not contain an adequate written description of the invention. To succeed, Nippon Shinyaku and NS Pharma must show by clear and convincing evidence that a person having ordinary skill in the field reading the patent specification as of the patent's effective filing date would not have recognized that it describes the full scope of the invention as it is finally claimed in the asserted claims. If a patent claim lacks adequate written description, it is invalid.

[40] Sarepta's Position: A neutral, generally accepted and legally correct jury instruction should be used.

Source: FCBA Model Patent Jury Instructions B.4.2(4.2a) (citing 35 U.S.C. § 112(a); Pre-AIA 35 U.S.C. § 112, ¶ 1; *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373-79 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 787 (2019); *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014); *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349-51 (Fed. Cir. 2013); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1287 (Fed. Cir. 2012); *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) ("While the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement." (internal citations omitted)); *PowerOasis, Inc. v. T-MOBILE USA, INC.*, 522 F. 3d 1299, 1306 (Fed. Cir. 2008); *Lizard Tech., Inc. v. Earth Res. Mapping Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 (Fed. Cir. 2004); *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253-55 (Fed. Cir. 2004); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000); *Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 1377-78 (Fed. Cir. 2000); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("In order for a disclosure to be inherent, however, the missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure."); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996)).

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent as of the effective filing date. The specification must describe the full scope of the claimed invention, including each element thereof, either expressly or inherently. A claimed element is disclosed inherently if a person having ordinary skill in the field as of the effective filing date would have understood that the element is necessarily present in what the specification discloses.

The written description does not have to be in the exact words of the claim. The requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. Adequate written description does not require either examples or an actual reduction to practice of the claimed invention. Written description is about whether the skilled reader of the patent can recognize that what was claimed corresponds to what was described; it is not about whether the patent owner has proven to the skilled reader that the invention works, or how to make it work.[41] However, a mere wish or plan for obtaining the claimed invention is not adequate written description. Rather, the level of disclosure required depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and other considerations appropriate to the subject matter.

[41] *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014) ("[W]ritten description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue."); *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 111 F.4th 1358, 1376 (Fed. Cir. 2004) (for written description, "a claimed invention need successfully operate only to some limited degree. It 'need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain circumstances.'") (quoting *Stiftung v. Renishaw PLC,* 945 F.2d 1173, 1180 (Fed. Cir. 1991)).

In this case, the asserted claim of the Wilton Patent is directed to a class of antisense oligonucleotides, which can be referred to as a "genus." One way to consider whether the combination of words, structures, figures, diagrams, formulas, etc. contained in the patent specification sufficiently describes the genus is to assess whether the specification includes a representative number of species falling within the scope of the claimed invention sufficient to encompass the breadth of the genus. The specification generally need not describe every species in a genus in order to satisfy the written description requirement. However, when there is substantial variation within the claimed genus, the specification must describe a sufficient variety of species to reflect the variation within the genus.

Another way to consider whether the written description is sufficient is to assess whether the patent specification identifies structural features common to the members of the claimed genus so that a person of ordinary skill in the art can "visualize or recognize" the members of the claimed invention. In the alternative, the written description requirement is satisfied in the above circumstance when there is an established correlation between structure and function described in the specification or known in the art at the time of filing.**]**

5.10 ENABLEMENT[42]

[Nippon Shinyaku's and NS Pharma's Proposal: A patent must disclose sufficient information to enable or teach persons of ordinary skill in the field of the invention to make and use the full scope of the claimed invention without undue experimentation. This requirement is known as the enablement requirement. If a patent is not enabled, it is invalid.

Nippon Shinyaku and NS Pharma contend that the asserted claim of the Wilton Patent is invalid for lack of enablement. To succeed with respect to each of the claims, Nippon Shinyaku and NS Pharma must show by clear and convincing evidence that the specification does not contain a sufficiently full and clear description to have allowed a person having ordinary skill in the art to make and use the full scope of the claimed inventions without undue experimentation.

The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be "unduly extensive." Some amount of experimentation to make and use the invention is allowable. However, it is not permissible to merely describe one's step-by-step, trial-and-error method for finding functional compounds in the genus, i.e. ASOs that induce exon 53 skipping, and call on scientists to create a wide range of candidate compounds and then screen each to see which has the claimed functionality.[43] A mere starting point from which a

[42] *Amgen Inc. v. Sanofi*, No. 14-1317, D.I. 812 (conforming edits).

[43] *Amgen Inc. v. Sanofi*, 598 U.S. 594, 613-14 (2023) (finding claims non-enabled where specification "describes step-by-step Amgen's own trial-and-error method for finding functional antibodies—calling on scientists to create a wide range of candidate antibodies and then screen each to see which happen to bind to PCSK9 in the right place and block it from binding to LDL Patent Officers").

scientist must engage in iterative, trial-and-error process to practice the claimed invention is not enabling.[44]

In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors, including:

1) The time and cost of any necessary experimentation;

2) How routine any necessary experimentation is in the field;

3) The presence or absence of working examples in the patent;

4) The amount and sufficiency of guidance presented in the patent;

5) The nature and predictability in the field;

6) The level of ordinary skill in the field; and

7) The breadth of the claims.

The above factors are neither mandatory nor exclusive, and no one or more of the above factors is alone conclusive. Rather, you must make your decision about whether or not the degree of any required experimentation is undue based upon all of the evidence presented to you. You should weigh these factors, and any other evidence related to this issue, and determine whether or not, in the context of this invention and the state of the art at the time of the applicable effective filing date, a person of ordinary skill in the art would need to experiment unduly to make and use the full scope of the claimed invention claimed in the Wilton Patent. For example, if practicing the full scope of a patent claim would have required excessive experimentation, even if that

[44] *Wyeth & Cordis Corp. v. Abbott Lab'ys*, 720 F.3d 1380, 1386 (Fed. Cir. 2013) ("Here, the specification similarly discloses only a starting point for further iterative research in an unpredictable and poorly understood field. . . . The resulting need to engage in a systematic screening process for each of the many rapamycin candidate compounds is excessive experimentation. We thus hold that there is no genuine dispute that practicing the full scope of the claims, measured at the filing date, required undue experimentation.").

experimentation was routine, the patent claim is invalid for lack of enablement.[45] In other words, where the art is unpredictable, and trial and error testing on large numbers of candidate compounds is required to identify compounds within the scope of a functionally defined claim for a vast array of possibilities encompassed by the claim, the disclosure is non-enabling even if each individual experiment is routine.[46]

In considering whether a patent complies with the enablement requirement, you must keep in mind that patents are written for persons of ordinary skill in the field of the invention. Thus, a patent need not expressly state information that persons of ordinary skill would be likely to know or could obtain, such as what was well known in the art and what would have already been available to the public. In addition, the patent disclosure need not enable persons of ordinary skill to make a commercially viable product or to otherwise meet the standards for success in the commercial marketplace.]

[**Sarepta's Proposal**:[47] The patent law contains certain requirements for the part of the patent called the specification. One of those requirements is called the enablement requirement.

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[45] *Idenix Pharms. LLC v. Gilead Sci., Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) ("Where, as here, 'practicing the full scope of the claims would have required excessive experimentation, even if routine,' the patent is invalid for lack of enablement." (quoting *Wyeth*, 720 F.3d at 1384)

[46] *Wyeth*, 720 F.3d at 1385-86; *Idenix*, 941 F.3d at 1163; *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1088 (Fed. Cir. 2021).

[47] Sarepta's Position: A neutral, generally accepted and legally correct jury instruction should be used.

Source: FCBA Model Patent Jury Instructions B.4.2(4.2b) (citing 35 U.S.C. § 112(a); Pre-AIA 35 U.S.C. § 112, ¶ 1; *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019); *Promega Corp. v. Life Techs. Corp.*, 773 F.3d 1338 (Fed. Cir. 2014), *rev'd and remanded on other grounds*, 137 S. Ct. 734 (2017); *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013) ("The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be 'unduly extensive.'" (quoting *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004) and *PPG Indus., Inc. v. Guardian Indus., Corp.*, 75

Nippon Shinyaku and NS Pharma contend that the asserted claim of the Wilton Patent is invalid because the specification does not "enable" the full scope of the claimed invention. To succeed, Nippon Shinyaku and NS Pharma must show by clear and convincing evidence that specification of the Wilton Patent does not contain a sufficiently full and clear description to have allowed a person having ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention as of the effective filing date, here June 28, 2005, allowing for a reasonable amount of experimentation.[48] If a patent claim is not enabled, it is invalid. A patent need only enable the subject matter that is claimed.[49]

F.3d 1558, 1564 (Fed. Cir. 1996)); *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013); *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377 (Fed. Cir. 2012); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) ("'The scope of the claims must be less than or equal to the scope of the enablement' to 'ensure[ ] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.'") (quoting *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999)); *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007) (full scope of claimed invention must be enabled); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (enabling the full scope of each claim is "part of the quid pro quo of the patent bargain" and suggesting express teaching against later-claimed embodiment may also be relevant); *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 690-92 (Fed. Cir. 2001); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345-46 (Fed. Cir. 2000); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (factors for determining undue experimentation)).

[48] *Amgen Inc. v. Sanofi,* 598 U.S. 594, 612 (2023) ("Decisions such as *Wood* and *Minerals Separation* establish that a specification may call for **a reasonable amount of experimentation** to make and use a patented invention.") (emphasis added).

[49] *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1371 (Fed. Cir. 2003), *cert. denied*, 114 S. Ct. 873 (2024) ("Again, because safety and efficacy are not recited in the claims, we need not deal with Liquidia's [enablement and written description] arguments."); *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1292 (D. Del. 1987), *aff'd*, 865 F.2d 1247 (Fed. Cir. 1989) ("The applicant is not required to include in his application support for matters not set forth in the claim."); *see also W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 (Fed. Cir. 1983).

The question of reasonable experimentation is a matter of degree, and what is required is that the extent of that experimentation is reasonable.[50] Some amount of experimentation to make and use the invention is allowable. In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors:

1. the time and cost of any necessary experimentation;
2. how routine any necessary experimentation is in the field of ASOs;
3. whether the patent discloses specific working examples of the claimed invention;
4. the amount of guidance presented in the patent;
5. the nature and predictability of the field of ASOs;
6. the level of ordinary skill in the field of ASOs; and
7. the nature and scope of the claimed invention.

No one or more of these factors is alone dispositive. Rather, you must make your decision about whether or not the degree of experimentation required is undue based upon all of the evidence presented to you. You should weigh these factors and determine whether or not, in the context of this invention and the state of the art at the time of the effective filing date, a person having ordinary skill would need to experiment unduly to make and use the full scope of the claimed invention.**]**

[50] *In re Starrett*, No. 2022-2209, 2023 WL 3881360, at *4 (Fed. Cir. June 8, 2023) ("Although a finding of enablement is not precluded by a skilled artisan's needing to engage in some measure of experimentation, ***the extent of that experimentation must be reasonable***. The determination as to whether the extent of experimentation is undue or reasonable is informed by the eight *Wands* factors.") (emphasis added).

6. DAMAGES

6.1 PATENT INFRINGEMENT DAMAGES - GENERALLY[51]

[Nippon Shinyaku and NS Pharma's Proposal: I will now give you some instructions related to damages. By instructing you on damages, I am not suggesting which party should win this case on any issue. These instructions are only to guide you in case you find that one claim of the NS Patents or Wilton Patent is valid.

The party asserting infringement has the burden to prove each element of its damages, including the amount of the damages, by a preponderance of the evidence. A party asserting infringement may only recover damages for the periods of time for which it held exclusive rights to the patents at issue. If the party asserting infringement possessed only a non-exclusive license to the patents, it cannot collect damages due to infringement during that period.[52] [53] While the

[51] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

[52] *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005) ("A nonexclusive license confers no constitutional standing on the licensee to bring suit or even to join a suit with the patentee because a nonexclusive licensee suffers no legal injury from infringement."); *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010) (a non-exclusive or "bare" licensee "suffers no legal injury from infringement"); *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) (where party did not have exclusive rights and "received only a 'bare license,'" it "has no entitlement under the patent statutes to itself collect lost profits damages for any losses it incurred due to infringement").

[53] Sarepta's Objection: The two preceding sentences of NS's proposal are particularly inappropriate as a jury instruction. To start, these sentences regard questions of contract interpretation, which are questions of law. Moreover, NS proposed an incomplete and misleading statement of the law. A party that has "the right to exclude others from making, using, and selling an invention described in the claims of a patent is constitutionally injured by another entity that makes, uses, or sells the invention." *Intell. Prop. Dev., Inc. v. TCI Cablevision of Calif., Inc.*, 248 F.3d 1333, 1346 (Fed. Cir. 2001). The Federal Circuit has explained that "constitutional standing is satisfied when a party holds at least one exclusionary right." *Univ. of S. Fla. Rsch. Found., Inc. v. Fujifilm Med. Sys. USA, Inc.*, 19 F.4th 1315, 1324 (Fed. Cir. 2021) (emphasis added). Exclusionary rights involve the ability to exclude others from practicing an invention or to "forgive activities that would normally be prohibited under the patent statutes." *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1342 (Fed. Cir. 2007).

party asserting infringement is not required to prove its damages with mathematical precision, it must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

The amount of damages you award must be adequate to compensate the party asserting infringement for any infringement. Parties asserting infringement may recover any damages they suffered as a result of the infringement.[54] The question you must decide is, had the infringer not infringed, what would the party asserting infringement holder have made?[55] Damages are not meant to punish an infringer.

[Sarepta's Proposal:[56] If you find that the claims of the NS Patents or Wilton Patent are not invalid, you must then consider what amount of damages to award to the party asserting

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To the extent that there remain any questions of fact for the jury to consider regarding Sarepta's entitlement to damages at the close of evidence, Sarepta submits that the parties should provide appropriately tailored jury instruction proposals at that time.

[54] *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654-55 (1983) ("At the same time, Congress sought to ensure that the patent owner would in fact receive full compensation for 'any damages' he suffered as a result of the infringement.") (quoting legislative history); *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995) (en banc) ("[T]he language of the statute is expansive rather than limiting . . . providing only a lower limit and no other limitation.").

[55] *Rite-Hite*, 56 F.3d at 1545 ("The question to be asked in determining damages is 'how much had the Patent Holder and Licensee suffered by the infringement. And that question [is] primarily: had the Infringer not infringed, what would the Patent Holder–Licensee have made?") (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964)).

[56] Nippon Shinyaku and NS Pharma's Objection: A neutral, generally accepted and legally correct jury instruction should be used. Further, Nippon Shinyaku and NS Pharma's instruction removes the mention of unenforceability, which is not an issue for the jury.

Sarepta's Position: Sarepta's proposal – taken from the FCBA Model Patent Jury Instructions – is generally accepted, legally correct, and even handed. Contrary to Nippon Shinyaku's and NS Pharma's objection above, Sarepta's proposal omits any mention of unenforceability.

Source: FCBA Model Patent Jury Instructions B.5(5.1) (citing 35 U.S.C. § 284; *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) ("What is taken from the owner of a utility patent (for purposes of assessing damages under § 284) is only the patented technology, and so the

infringement. I will now instruct you about the measure of damages. By instructing you on damages, I am not suggesting which party should win this case, on any issue. If you find that the claims of the NS Patents are invalid, then Nippon Shinyaku is not entitled to any damages. If you find that the claim of the Wilton Patent is invalid, then Sarepta and UWA are not entitled to any damages.

The damages you award must be adequate to compensate the party asserting infringement for the infringement. They are not meant to punish an infringer. Your damages award, if you reach this issue, should put the party asserting infringement in approximately the same financial position that it would have been in had the infringement not occurred.

The party asserting infringement has the burden to establish the amount of its damages by a preponderance of the evidence. In other words, you should award only those damages that the party asserting infringement establishes that it more likely than not has suffered. While the party asserting infringement is not required to prove the amount of its damages with mathematical precision, it must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

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value to be measured is only the value of the infringing features of an accused product."); *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014) ("No matter what the form of the royalty, a patentee must take care to seek only those damages attributable to the infringing features."); *Calico Brand, Inc. v. Ameritek Imps., Inc.*, 527 F. App'x. 987, 996 (Fed. Cir. 2013) ("lost profits must be tied to the intrinsic value of the patented feature"); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) ("the trial court must carefully tie proof of damages to the claimed invention's footprint in the market place"); *Dow Chem. Co. v. Mee Indus.*, *Inc.*, 341 F.3d 1370, 1381-82 (Fed. Cir. 2003); *Integra Lifesciences I*, *Ltd. v. Merck KGaA*, 331 F.3d 860, 870 (Fed. Cir. 2003); *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999); *Maxwell v. J. Baker*, *Inc.*, 86 F.3d 1098, 1108-09 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc); *Lam*, *Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983)).

There are different types of damages that the party asserting infringement may be entitled to recover. In this case, Nippon Shinyaku, and Sarepta and UWA seek lost profits and/or a reasonable royalty. Lost profits consist of any actual reduction in business profits the party asserting infringement suffered as a result of the other party's infringement. A reasonable royalty is defined as the money amount the party asserting infringement and the other party would have agreed upon as a fee for use of the invention at the time just prior to when infringement began. But, regardless of the type of damages you may choose to award, you must be careful to ensure that award is no more and no less than the value of the patented invention.

I will give more detailed instructions regarding damages shortly. Note, however, that the party asserting infringement is entitled to recover no less than a reasonable royalty for each infringing act.]

6.2 TYPES OF DAMAGES[57] [58]

[Nippon Shinyaku and NS Pharma's Proposal: There are different types of damages that are available for patent infringement. In this case, each of Nippon Shinyaku and Sarepta and UWA may describe damages they are seeking for patent infringement as lost profits and/or a reasonable royalty. Lost profits damages compensate the party asserting infringement for the additional profits that it would have earned if the accused infringer had not infringed. You may hear this referred to as the "but for" test. I will discuss lost profits in more detail shortly.

I will also discuss a reasonable royalty later in more detail. Generally, a reasonable royalty is defined by the patent laws as a reasonable amount that someone wanting to use the patented invention should expect to pay to the party asserting infringement and that party should expect to receive. A reasonable royalty is the minimum amount of damages that a party asserting infringement may recover.]

[Sarepta's Proposal:[59] N/A.]

[57] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

[58] Nippon Shinyaku and NS Pharma believe it is less confusing for the jury to keep these as separate sub-headings.

[59] Sarepta's Position: This instruction is subsumed within Sarepta's proposed instruction 6.1.

6.3 LOST PROFITS – "BUT FOR" TEST[60]

I will first instruct you about lost profits damages. To recover lost profits (as opposed to reasonable royalties), the party asserting infringement must show a causal relationship between the infringement and party asserting infringement's loss of profit. In other words, the party asserting infringement must show that, but for the infringement, there is a reasonable probability that the party asserting infringement would have earned higher profits. To show this, the party asserting infringement must prove that, if there had been no infringement, it would have made some portion of the sales that the alleged infringer made of the infringing product.

Each party must prove this by a preponderance of the evidence, i.e., it is more likely than not that the party asserting infringement would have made additional profits if the accused infringer had not infringed.[61] Part of your job is to determine what the customer who purchased the accused products from the accused infringer would have done if the alleged infringement had not occurred.[62] It is important to remember that the profits I have been referring to are the profits allegedly lost by the party asserting infringement, not the profits, if any, made by the accused infringer on the allegedly infringing sales.[63]

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[60] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.2 (similar).

[61] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW).

[62] *Id.*

[63] *Id.*

A party establishes "but for" causation and that it is entitled to an award of its lost profits if you find that it has proven each of the following four factors by a preponderance of the evidence:[64]

1. That there was demand for the patented product or method;
2. That there were no available, acceptable, noninfringing substitute products, or, if there were, the market share of the number of the sales made by the alleged infringer that the party asserting infringement would have made, despite the availability of other acceptable noninfringing substitutes;
3. That the party asserting infringement had the manufacturing and marketing capacity to make any infringing sales actually made by the alleged infringer and for which the party asserting infringement seeks an award of lost profits—in other words, that the party asserting infringement was capable of satisfying the demand;
4. The amount of profit that the party asserting infringement would have made if the alleged infringer had not infringed.

[64] *Id.*

6.4 LOST PROFITS – DEMAND FOR PATENTED PRODUCT[65]

Demand for the patented product can be proven by significant sales of a party asserting infringement's patented product or significant sales of an infringing product containing the patented features.

[65] Source: FCBA Model Patent Jury Instructions 5.2 (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009).

6.5 LOST PROFITS - ACCEPTABLE NON-INFRINGING SUBSTITUTES[66]

To be an "acceptable, noninfringing substitute," a product must have the advantages of the patented invention that were important to people who purchased an alleged infringer's product. If purchasers of an alleged infringer's product were motivated to buy that product because of features available only from that product and a party asserting infringement's patented product, then some other, alternative product is not an acceptable substitute, even if it otherwise competed with a party asserting infringement's and an alleged infringer's products. On the other hand, if the realities of the marketplace are that competitors other than the party asserting infringement would likely have captured the sales made by the infringer, despite a difference in the products, then the party asserting infringement is not entitled to lost profits on those sales.

[66] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.2.

6.6 LOST PROFITS – AVAILABILITY OF NONINFRINGING SUBSTITUTES

[**Nippon Shinyaku and NS Pharma's Proposal**:[67] This instruction should not be included]

[**Sarepta's Proposal**:[68] An alternative product may be considered "available" as a potential substitute even if the product was not actually on sale during the infringement period. Factors suggesting the alternative was available include whether the material, experience, and know-how to make or use the alleged substitute were readily available at the time of infringement. Factors suggesting the alternative was not available include whether the material was of such high cost as to render the alternative unavailable and whether an alleged infringer had to design or invent around the patented technology to develop an alleged substitute.]

[67] Nippon Shinyaku and NS Pharma object to the inclusion of this unnecessary instruction.

[68] Sarepta's Position: This instruction (derived from the FCBA Model) properly instructs the jury on the law related to the second *Panduit* factor (listed in agreed instruction 6.3), just as agreed instruction 6.5 does.

Source: FCBA Model Patent Jury Instructions 5.2 (citing *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999) (holding that an unused, but available, noninfringing process was an acceptable substitute); *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1123 (Fed. Cir. 2003) ("The record shows that Lextron did not have the necessary equipment, know-how, and experience to make the [alternative] machine at the time of infringement.")).

6.7 LOST PROFITS – CAPACITY[69]

The third factor asks whether the party asserting infringement had the manufacturing and marketing ability to actually make the sales it allegedly lost due to the accused infringers' infringement. The party asserting infringement must prove that it was more likely than not that it would have had the capacity to manufacture enough products to make those additional sales, as well as the marketing capability to make those additional sales.

[69] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

6.8 LOST PROFITS – AMOUNT OF PROFIT[70]

To show entitlement to lost profits, the party asserting infringement must prove by a preponderance of the evidence the amount of profits it lost.[71]

A party asserting infringement may calculate its lost profits on lost sales by computing the lost revenue for sales it claims it would have made but for the infringement and subtracting from that figure the amount of additional costs or expenses it would have incurred in making those lost sales, such as cost of goods, sales costs, packaging costs, and shipping costs. Certain fixed costs that do not vary with increases in production or scale, such as taxes, insurance, rent, and administrative overhead, should not be subtracted from a party asserting infringement's lost revenue.

[70] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.2 (citing *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11 (Fed. Cir. 1984)).

[71] Source: *Promega Corp. v. Life Techs. Corp.*, 875 F.3d 651, 660 (Fed. Cir. 2017) ("Damages 'must not be left to conjecture by the jury. They must be proved, and not guessed at.'") (*quoting Philp v. Nock*, 84 U.S. (17 Wall.) 460, 462 (1873)); *id.* ("When a patentee seeks lost profits as the measure of damages, 'the patent holder bears the burden of proving the ***amount*** of the award.'") (emphasis in original) (*quoting Minco, Inc. v. Combustion Eng'g, Inc.*, 95 F.3d 1109, 1118 (Fed. Cir. 1996)).

6.9 LOST PROFITS – INEXORABLE FLOW

[**Nippon Shinyaku and NS Pharma's Proposal**:[72] This instruction should not be included]

[**Sarepta's Proposal**:[73]

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[72] Nippon Shinyaku and NS Pharma's Position: Nippon Shinyaku and NS Pharma object to the inclusion of this instruction. As explained in Nippon Shinyaku's opposition to Sarepta's motion for summary judgment, (D.I. 462), a showing under the "inexorable flow" doctrine is not required because—contrary to Sarepta's characterization in this instruction—Nippon Shinyaku is seeking to recover profits it has itself lost as the sole supplier of VILTEPSO to the United States. Even if "inexorable flow" were implicated, Sarepta's instruction inappropriately (1) states that "Nippon Shinyaku claims the lost profits of its subsidiary NS Pharma" (which Nippon Shinyaku does not and which is at most a question of fact); and (2) provides the jury no guidance regarding what to consider as evidence of inexorable flow, such as "contractual, structural, or historical" evidence supporting the flow. *See Schwendimann v. Arkwright Advanced Coating, Inc.*, 220 F. Supp. 3d 953, 975 (D. Minn. 2016) (quoting *Kowalski v. Mommy Gina Tuna Resources*, 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008)).

[73] Sarepta's Position: As explained in Sarepta's Motion for Summary Judgment of No Lost Profits (D.I. 409 at 8-9), the Federal Circuit has never affirmed an award of lost profits based on the profits of a non-party to an infringement claim flowing inexorably to its related patent-holding entity who itself does not sell a product in the United States. *See, e.g., Fujitsu Ltd. v. Tellabs, Inc.*, 539 F. App'x 1005, 1007 (Fed. Cir. 2013) (declining appeal regarding inexorable flow lost profits on procedural grounds); *see also Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1375 (Fed. Cir. 2015), *vacated sub nom. on other grounds Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.*, 577 U.S. 1099 (2016) ("a patentee may not claim, as its own damages, the lost profits of a related company."). Subsequently, some courts have held that the inexorable theory is legally wrong. *See, e.g., Mars, Inc. v. TruRx LLC*, Case No. 6:13-cv-526, 2016 WL 4061981, at *2 (E.D. Tex. Apr. 29, 2016) ("To date, no case decided by the Federal Circuit has allowed a patentee to recover the lost profits of a related company as its own under the inexorable flow theory."); *Copperhead Indus., Inc. v. Changer & Dresser, Inc.*, Case No. 1:18-cv-01228, 2020 WL 429485, at *2 (N.D. Ala. Jan. 28, 2020). The Court did not explicitly address this legal issue when it denied Sarepta's Motion for Summary Judgment of No Lost Profits, stating only that "it appear[s] that there is a genuine dispute of material fact as to whether NS Japan has itself suffered damages in the form of lost profits." D.I. 548. To the extent the jury is instructed on lost profits with respect to Nippon Shinyaku's claim, which is based on the alleged lost profits of its subsidiary NS Pharma (*see* D.I. 409 at 8-13; D.I. 490 at 5-10), this instruction should be included. It clarifies for the jury that Nippon Shinyaku has the burden to show that the lost profits it seeks to recover are its, and not those of its subsidiary NS Pharma. The instruction also clarifies that, if the jury determines that Nippon Shinyaku is seeking recovery of its subsidiary's lost profits, Nippon Shinyaku has the further burden to prove that the lost profits of that subsidiary inexorably flow to Nippon Shinyaku.

To be entitled to lost profits, a party must show that the lost profits come from the lost sales of a product the party itself was selling.[74] A party may not claim, as its own damages, the lost profits of a related entity, unless it shows those profits inexorably flow to it.[75] Inexorable means that the profits flow automatically from the related entity to the party; in other words, the related entity's profits *are* the party's profits.[76] Inexorable flow cannot be proven merely by an agreement to transfer profits or by ownership and control of a subsidiary by a parent.[77]]

Source: *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008) ("Because we conclude that MEI's profits did not—as Mars argues—flow inexorably to Mars, we, like the *Poly-America* court, need not decide whether a parent company can recover on a lost profits theory when profits of a subsidiary actually *do* flow inexorably up to the parent."); *Intuitive Surgical, Inc. v. Auris Health, Inc.*, 2021 WL 3662842, at *3-4 (D. Del. Aug. 18, 2021) (granting summary judgment of no lost profits for lack of proof on inexorable flow).

[74] Source: *Kaneka Corp. v. Designs for Health, Inc*., No. 21-209-WCB, Doc. 141 at 25 (D. Del. Mar. 3, 2023) (quoting *Warsaw Orthopedic, Inc. v. NuVasive, Inc.,* 778 F.3d 1365, 1376 (Fed. Cir. 2015)*, vacated on other grounds, Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.,* 577 U.S. 1099, 136 S. Ct. 893, 193 L. Ed. 2d 785 (2016); *Poly-Am., L.P. v. GSE Lining Tech*., *Inc*., 383 F.3d 1303, 1311 (Fed. Cir. 2004).

[75] Source: *Mars, Inc. v. Coin Acceptors, Inc*., 527 F.3d 1359, 1367 (Fed. Cir. 2008).

[76] Source: *Advanced Fiber Techs. (AFT) Tr. v. J & L Fiber Servs., Inc*., No. 1:07-CV-1191 LEK/DEP, 2015 WL 1472015, at *25 (N.D.N.Y. Mar. 31, 2015).

[77] Source: *Fujitsu Ltd. v. Tellabs, Inc*., No. 09 C 4530, 2013 WL 2285794, at *8 (N.D. Ill. May 23, 2013); *Kowalski v. Mommy Gina Tuna Res*., 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008).

6.10 DAMAGES – REASONABLE ROYALTY[78]

Nippon Shinyaku, and Sarepta and UWA are also each seeking damages in the amount of a reasonable royalty.

If you find that a patent claim is not invalid, the party asserting infringement is entitled to at least a reasonable royalty to compensate it for that infringement.

If you find that the party asserting infringement has not proved its claim for lost profits, or has proved its claim for lost profits for only a portion of the infringing sales, then you must award that party a reasonable royalty for all infringing sales for which it has not been awarded lost profits damages.

A royalty is a payment made to a party asserting infringement in exchange for the right to make, use, or sell the claimed invention. A reasonable royalty is the royalty payment that would have resulted from a hypothetical negotiation between the party asserting infringement and the alleged infringer just before the infringement began.

The reasonable royalty award must be based on the incremental value that the patented invention adds to the end product. When the infringing product includes both patented and unpatented features, measuring this value requires a determination of the value added by the patented features. The royalty rate must reflect the value attributable to the infringing features, and no more.

In considering this hypothetical negotiation, you should focus on what the expectations of the party asserting infringement and the alleged infringer would have been if they had entered into an agreement at that time, and if they had acted reasonably in their negotiations. In determining

[78] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.5, 5.6 (similar).

this, you must assume that both parties to the hypothetical negotiation believed the patent was valid and infringed and that both parties were willing to enter into an agreement. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation just prior to the first infringement. In determining the reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began.

6.11 REASONABLE ROYALTY – FACTORS[79]

In determining a reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began. Some of the kinds of factors that you may consider in making your determination are:

1. Any royalties received by the party asserting infringement for licensing others under their respective asserted patents, proving or tending to prove an established royalty;

2. The rates paid by the accused infringer to license other patents comparable to the asserted patents.

3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of its territory of with respect to whom the manufactured product may be sold.

4. The licensor's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity.

5. The commercial relationship between the licensor and the licensee, such as whether or not they are competitors in the same territory in the same line of business.

6. The effect of selling the patented product in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such collateral sales.

7. The duration of the asserted patents and the term of the license.

[79] Source: FCBA Model Patent Jury Instructions B.5(5.8) (edited to list all *Georgia-Pacific* factors); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (similar); *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

8. The established profitability of the patented product; its commercial success; and its current popularity.

9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results.

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

11. The extent to which the accused infringer has made use of the invention; and any evidence that shows the value of that use.

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

13. The portion of the profit that arises from the patented invention itself as opposed to profit arising from unpatented features, such as unpatented features, business risks, or significant features or improvements added by the accused infringer.

14. The opinion testimony of qualified experts.

15. The amount that a licensor and a licensee (such as the accused infringer) would have agreed upon (at the time the infringement began) if both sides had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article made by the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a party asserting infringement who was willing to grant a license.

16. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

No one factor is dispositive, and you can and should consider the evidence that has been presented to you in this case on each of these factors.

6.12 DAMAGES – TIMING[80]

The relevant date for the hypothetical reasonable royalty negotiation is at the time the infringement began.

Damages are not based on a hindsight evaluation of what happened, but on what the parties to the hypothetical license negotiations would have agreed upon. Nevertheless, evidence relevant to the negotiation is not necessarily limited to facts that occurred on or before the date of the hypothetical negotiation. You may also consider information the parties would have foreseen or estimated during the hypothetical negotiation, which may under certain circumstances include evidence of usage after infringement started, license agreements entered into by the parties shortly after the date of the hypothetical negotiation, profits earned by the infringer, and non-infringing alternatives.

[Sarepta's Proposal:[81] [82] In determining the amount of damages, you must determine when the damages began. Damages commence on the date that the alleged infringer has both infringed and been notified of the alleged infringement of the asserted patent:

[80] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

[81] Nippon Shinyaku and NS Pharma's Objection: A neutral, generally accepted and legally correct jury instruction should be used. Nippon Shinyaku and NS Pharma object to the inclusion of this portion of the instruction.

Source: FCBA Model Patent Jury Instructions B.5(5.10).

[82] Sarepta's Position: Sarepta's proposed instruction includes language from the Federal Circuit Bar Association Model Patent Instructions and instructs the jury evenly as to relevant time periods for damages issues in this case.

With respect to the NS Patents, the parties agree that the date of commencement of damages for lost profits was August 19, 2020. The parties further agree that the hypothetical negotiation would have occurred around December 2019.[83]

With respect to the Wilton Patent, the parties agree that the date of commencement of damages for lost profits was August 19, 2020. The parties further agree that the hypothetical negotiation would have occurred in August 2020.[84]]

[83] *Sunoco Partners Marketing & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, D.I. 767.

[84] *Sunoco Partners Marketing & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, D.I. 767.

6.13 REASONABLE ROYALTY – COMPARABLE AGREEMENTS

[**Nippon Shinyaku and NS Pharma's Proposal**: This instruction should not be included.]

[**Sarepta's Proposal (additional instruction)**:[85] [86] When determining a reasonable royalty, you may consider evidence concerning the amounts that other parties have paid for rights to the patents in question, or for comparable rights to similar technologies. A license agreement need not be perfectly comparable to a hypothetical license that would be negotiated between the parties in order for you to consider it. However, if you choose to rely upon evidence from any license agreements, you must account for any differences between those licenses and the hypothetically negotiated license between the parties in terms of the technologies and economic circumstances of the contracting parties, when you make your reasonable royalty determination.]

[85] Nippon Shinyaku and NS Pharma objects to inclusion of this instruction.
[86] Sarepta's Position: This instruction – taken from the AIPLA Model Patent Jury Instructions – explains to the jury settled law regarding the need to prove comparability of licenses to determine a reasonable royalty damages award.
[86] Sarepta's Position: This instruction – taken from the AIPLA Model Patent Jury Instructions – explains to the jury settled law regarding the need to prove comparability of licenses to determine a reasonable royalty damages award.

Source: AIPLA Model Patent Jury Instructions 10.2.5.9 (conforming edits); *Sunoco Partners Marketing & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, D.I. 767.

7. DELIBERATION AND VERDICT

7.1 INTRODUCTION[87]

I have concluded my instructions on the law. All of the instructions I gave you previously today - as well as earlier during trial - still apply, and you will have a copy of the instructions with you in the jury room.

Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

[87] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (slight edits).

7.2 UNANIMOUS VERDICT[88]

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so consistent with your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A verdict form has been prepared for you. I will review that document with you in a moment. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. You will then return to the courtroom and my deputy will read aloud your verdict.

And I will remind you that nothing said in these instructions, and nothing in the form of a verdict, is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is your sole and exclusive duty and responsibility.

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[88] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (slight edits).

7.3 DUTY TO DELIBERATE[89]

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach a unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say.

Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that - your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

If any member of the jury took notes, let me remind you that notes are not given any greater weight than the memory or impression of each juror as to what the testimony may have been. Whether you took notes or not, each of you must form and express your own opinion as to the facts of the case.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds. Listen carefully to what the other jurors have to say, and then decide for yourself.

I am going to remind you now, if you go home this evening and resume your deliberations on the next business day, you are not to talk about the case among yourselves or with anyone else

[89] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (similar); *Cap-XX, Ltd. v. Maxwell, Techs., Inc.*, C.A. No. 19-1733, D.I. 314 (JLH) (similar).

during the evening recess. You may not read or listen to any news about the case in a newspaper, online, through any news apps, on the radio, through any social media, in blogs, or on television during the evening recess.

7.4 SOCIAL MEDIA[90]

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, a cell phone, smartphone, iPhone, iPad, tablet or computer, the Internet, any Internet service, any text or instant messaging service, any Internet chat room, blog or website such as Facebook, LinkedIn, YouTube, Instagram, Snapchat or Twitter/X to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

[90] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (conforming edits).

7.5 EQUAL STANDING[91]

Remember that in a very real way you are the judges of the facts. Your only interest is to seek the truth from the evidence in the case. You should consider and decide this case as a dispute between persons of equal standing in the community, of equal worth, and holding the same or similar stations in life. A corporation is entitled to the same fair trial as a private individual. All persons, including corporations, and other organizations stand equal before the law and are to be treated as equals.

[91] Source: *ART+COM Innovationpool GmbH v. Google LLC*, C.A. No. 24-217, D.I. 410 (TBD).

7.6 COURT HAS NO OPINION[92]

Let me finish by repeating something I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.

Finally, if I have read any of these instructions inconsistently with the written text, you are to rely on the written instructions in your deliberations.

[92] Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *CAO Lighting. Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (similar); *Cap-XX, Ltd. v. Maxwell, Techs., Inc.*, C.A. No. 19-1733, D.I. 314 (JLH) (similar).